

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA**

HEALTHIER CHOICES
MANAGEMENT CORP.,

Plaintiff,

v.

PHILIP MORRIS USA, INC. and
PHILIP MORRIS PRODUCTS S.A.,

Defendants.

Case No. 1:20-cv-04816-TCB

PLAINTIFF'S OPPOSITION TO DEFENDANTS' MOTION TO DISMISS
UNDER FED. R. CIV. P. 12(b)(6)

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Plaintiff Healthier Choices Management Corp. (“Healthier Choices”) files this response pursuant to N.D. Ga. L. Civ. R. 7.1B in Opposition to Defendants Philip Morris USA, Inc. (“PMI”) and Philip Morris Products S.A.’s (“PMP”) (collectively, “Defendants”) Motion to Dismiss Under Federal Rule of Civil Procedure (“Fed. R. Civ. P.” or “Rule”) 12(b)(6) (D.E. 31, “Defendants’ Motion”), and states as follows:

The Court need only read the Introduction to Defendants’ Motion to conclude that it must be denied. While styled as a motion to dismiss under Rule 12(b)(6), Defendants appear to be moving for a judgment on the pleadings. But to get there, Defendants need the Court to not only undertake claim construction of Healthier Choices’ patent, but also, to resolve numerous factual issues in Defendants’ favor. Neither is appropriate at the pleading stage.

I. INTRODUCTION

Healthier Choices’ Complaint alleges that Defendants infringe, either literally or under the doctrine of equivalents, Healthier Choices’ U.S. Patent No. 10,561,170 (“the ’170 patent”), titled “Electronic Pipe” and attached as Exhibit A to the Complaint. D.E. 1-1.

Defendants’ Motion misses the mark for several reasons. First, Healthier Choices’ well-pleaded Complaint complies with the pleading requirements of this Court and *Iqbal/Twombly*, with sufficient detail to put Defendants on fair notice of the plausible claims asserted and statements in support thereof. Specifically,

Healthier Choices relies on admissions in documents Defendants themselves submitted to the FDA which, at best, show that the IQOS® “Tobacco Heating System” (“IQOS® system”) is 97% combustion-free, thereby admitting that some combustion occurs. Second, and just as fatal to Defendants’ Motion, the FDA Scientific Review appended to their motion as allegedly proving that the IQOS® system is combustion-free, in fact shows that FDA merely concluded that Defendants’ data submitted to the FDA “suggest[s] that combustion does not occur.” The FDA’s statement relied upon by Defendants here neither refutes the “97% combustion-free” statement set forth in the Complaint, nor does it establish non-infringement of ’170 patent, claim 5 of which requires, *inter alia*, only “at least partially combusting the combustible material.”

Third, Defendants’ Motion clearly raises a genuine dispute as to the meaning of the term “combustion,” as it is used in the claims of the ’170 patent. Further, Defendants attempt to impermissibly rely on the FDA Scientific Review to advance a construction for the term “combustion” that is unquestionably disputed for purposes of their Rule 12(b)(6) motion. Specifically, Defendants’ reliance on the FDA Scientific Review is misplaced and irrelevant to the construction for any term in the ’170 patent because it is (i) impermissible to conflate FDA’s use of the term “combustion” with an analysis of what that term means in the context of the ’170 patent; and (ii) the document itself is dated years after the patent filing date and does

not inform one skilled in the art of the meaning of “combustion.” Indeed, the term “combustion” is not defined anywhere in the FDA Scientific Review. Moreover, FDA’s approval of Defendants’ IQOS® system as a “heat-not-burn” device does not answer the question of whether a small amount of “combustion”—as that term is used in the ’170 patent—nonetheless occurs in Defendants’ IQOS® system. This is why reliance on such extrinsic evidence is disfavored when construing the claims of a patent.

Moreover, and critical to this analysis, the Federal Circuit has repeatedly held that claim construction issues are not proper for resolution at the Rule 12(b)(6) motion stage. Defendants raise this claim construction dispute under the guise of judicial notice when in fact, Defendants boldly cite to extrinsic evidence for the truth of whether combustion occurs—a fact-in-dispute that is clearly inappropriate for the Court to decide at the pleading stage.

Healthier Choices’ well-pleaded Complaint aptly notes that Defendants’ IQOS® system in combination with an IQOS® Tobacco Stick (HeatStick) infringes at least claim 1 of the ’170 patent, either literally or under the doctrine of equivalents. D.E. 1 (“Complaint”), ¶¶ 26-32, 35-37, 42, 44-47, 49, 54. Further, Healthier Choices’ Complaint alleges Defendants know and specifically intend for the IQOS® system to be used in a manner that meets the limitations of at least claim 5 of the ’170 patent. Complaint at ¶¶ 27, 43-44, 50-56. Specifically, Defendants infringe

directly and/or indirectly by loading combustible material into a material reservoir and initiating a combustion reaction in the combustible material reservoir. Complaint at ¶¶ 45-46, 50-52. As to inducement, Defendants seem to be confused about the difference between dismissal of the case and any potential limitation regarding Plaintiff's damages. In any event, Defendants' claim fails because post-suit knowledge is sufficient to assert inducement at the pleading stage.

At bottom, Defendants' Motion seeks to impermissibly expand the well-understood pleading requirements of Rule 8 and *Iqbal/Twombly* to include requirements not supported by the law of this circuit. For the reasons set forth below, Plaintiff Healthier Choices' well-pleaded Complaint complies with the pleading requirements of this Court and controlling case law, with sufficient detail to put Defendants on fair notice of the plausible claims asserted and statements in support thereof.

II. FACTS

On November 18, 2016, PMP submitted a Modified Risk Tobacco Product Application ("MRTPA") for the IQOS® system to the FDA, requesting modified risk tobacco product orders under sections 911(g)(1) (risk modification order) and 911(g)(2) (exposure modification order) of the Food Drug & Cosmetic Act ("FD&C Act"). Executive Summary (D.E. 1-10 (MRTPA, § 2.7 Executive Summary)) at 9; the FDA Scientific Review (D.E. 31-2 (FDA's Scientific Review of MRTPA under

Section 911(d) of the FD&C Act)) at 7.¹ Neither the Executive Summary nor the FDA Scientific Review state that combustion cannot and does not occur under normal operation of Defendants’ IQOS[®] system, nor do the documents state that the Applicant, PMP, requested FDA to confirm that the IQOS[®] system cannot initiate a combustion reaction. *Compare* Executive Summary at 34 (requesting, as one “secondary objective[, to] confirm the absence of combustion”) *with* FDA Scientific Review at 21 (citing Defendants’ evidence and conclusions to “suggest that combustion does not occur . . . when [the IQOS system] is used as intended,” limiting FDA’s conclusion to “[t]he IQOS system heats tobacco but does not burn it”).

On or around May 24, 2017, Defendant PMP filed Pre-Market Tobacco Product Applications (“PMTA”) for its IQOS[®] system at FDA, and received approval to import and distribute, and in concert with PMI, market, offer for sale, sell, and/or instruct customers how to use the IQOS[®] system in the United States. Complaint at ¶¶ 33-34. Beginning in October 2019, Defendants began importing, distributing, marketing, offering for sale, selling, and commercially using the IQOS[®] system in the United States, including in this District. Complaint at ¶¶ 35, 37. On November 30, 2020, Plaintiff Healthier Choices filed this patent infringement action

¹ For convenience, consistency with Healthier Choices’ Complaint and Defendants’ Motion, and ease of reference, pin cites to the Executive Summary and the FDA Scientific Review refer to the originally paginated submissions, not the newly paginated docket entries that were filed with the Court.

under the United States patent laws, Title 35, United States Code §§ 100, *et seq.*, including 35 U.S.C. § 271.

Healthier Choices filed its Complaint alleging Defendants' direct and indirect infringement of the '170 patent, either literally or under the doctrine of equivalents. Complaint at ¶¶ 42-57. Specifically, Defendants' manufacture, use, sale, offer for sale, and/or importation of the IQOS® system in combination with HeatSticks directly infringes one or more claims of the '170 patent. Complaint at ¶¶ 8, 9, 20, 21, 53-55. Further, Healthier Choices' Complaint identifies Defendants' indirect infringement. Complaint at ¶¶ 43-46, 48, 50-56. Specifically, Defendants advertise and promote the IQOS® system and/or instructions-for-use to potential and actual purchasers of the IQOS® system, demonstrating Defendants induce and/or contribute to infringement of one or more claims of the '170 patent. Complaint at ¶¶ 8, 9, 20, 21, 53-55.

Healthier Choices consented to Defendants' two motions to extend their time to answer the Complaint (D.E. 17 & D.E. 22), which were granted on December 29, 2020, and January 19, 2020, respectively. *See* D.E. 18 & D.E. 23. On February 25, 2021, Defendants filed the instant motion to dismiss for failure to state a claim under Fed. R. Civ. P. 12(b)(6). D.E. 31. And on March 10, 2021, the Court granted an eleven-day extension to file both Healthier Choices' Response to Defendants' Motion, and Defendants' Reply to Healthier Choices' Response. *See* D.E. 35.

III. LEGAL STANDARD

Rule 8(a)(2) requires only “‘a short and plain statement of the claim showing that the pleader is entitled to relief,’ in order to ‘give the defendant fair notice of what the . . . claim is and the grounds upon which it rests.’” *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (quoting *Conley v. Gibson*, 355 U.S. 41, 47 (1957)). There is no requirement for the plaintiff to “prove its case at the pleading stage.” *In re Bill of Lading Transmission & Processing Sys. Patent Litig.*, 681 F.3d 1323, 1339 (Fed. Cir. 2012). When addressing a motion to dismiss, “the Court’s consideration is limited to the four corners of the complaint” and attachments thereto. *Apotex, Inc. v. UCB, Inc.*, No. 12-cv-60706, 2013 WL 12091641, at *2 (S.D. Fla. Jan. 17, 2013) (citing *St. George v. Pinellas Cty.*, 285 F.3d 1334, 1337 (11th Cir. 2002)).

At the pleading stage, Rules 8(a)(2) and 12(b)(6) merely require a plaintiff provide “only enough facts to state a claim for relief that is plausible on its face.” *Twombly*, 550 U.S. at 570. Statements in the complaint are accepted as “true” and all plausible inferences derived from those facts are evaluated in favor of the plaintiff. *Spanakos v. Aronson*, No. 17-cv-80965, 2018 WL 2392011, at *2 (S.D. Fla. Apr. 2, 2018) (citing *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) and *Twombly*, 550 U.S. at 554-55). Such a motion is defeated when “the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is

liable for the misconduct alleged.” *Iqbal*, 556 U.S. at 679 (citing *Twombly*, 550 U.S. at 556).

With respect to patent infringement, proving infringement requires the patentee demonstrate that the IQOS[®] system meets each claim limitation literally or under the doctrine of equivalents. Specifically, the two-step infringement analysis includes “determining the meaning and scope of the patent claims[,]” “known as claim construction[,]” and then “comparing the properly construed claims to the [accused infringing product].” *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995). The first step, claim construction, is an issue of law that is exclusively within the province of the court. *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 574 U.S. 318, 325 (2015); *Warner-Lambert Co. v. Teva Pharms. USA, Inc.*, 418 F.3d 1326, 1340 (Fed. Cir. 2005). The second step, comparing the properly construed claims to the accused infringing product to determine infringement, is a question of fact. *Deering Precision Instruments, L.L.C. v. Vector Distrib. Sys., Inc.*, 347 F.3d 1314, 1324 (Fed. Cir. 2003).

To state a claim for patent infringement, a plaintiff need only include: “1) an allegation of jurisdiction; 2) a statement that the plaintiff owns the patent; 3) a statement that the defendant has been infringing the patent by making, selling, and using [the device] embodying the patent; 4) a statement that the plaintiff has given the defendant notice of its infringement; and 5) a demand for an injunction and damages.” *Auburn Univ. v. IBM*, 864 F. Supp. 2d 1222, 1225, 2012 U.S. Dist. LEXIS 76709, *10 (M.D. Ala. June 4, 2012); *Gelsomino v. Horizon Unlimited, Inc.*, No. 07-cv-80697, 2008 U.S. Dist. LEXIS 68907, at *7 (S.D. Fla. Sept. 9, 2008). Any further inquiry, courts have routinely held, is inappropriate for dismissal under Rule 12(b)(6), especially where the parties raise a claim construction dispute that could affect the court’s analysis. *Nalco Co. v. Chem-Mod, LLC*, 883 F.3d 1337, 1349 (Fed. Cir. 2018); *see In re Bill of Lading Transmission and Processing Sys. Patent Litig.*, 681 F.3d at 1343, n.13 (Fed. Cir. 2012) (citation omitted) (explaining that it would be “inappropriate” for a district court to engage in “claim construction at the pleading stage—with no claim construction process undertaken.”); *Fujitsu Ltd. v. Belkin Int’l, Inc.*, 782 F. Supp. 2d 868, 889-90 (N.D. Cal. 2011) (“If the Court were to construe the Ozawa Patent’s claims at the motion to dismiss stage, it would be starting the process of evaluating the merits of Fujitsu’s case [A] motion to dismiss is not the proper time to raise claim construction arguments.”).

IV. ARGUMENT

Federal Circuit and regional circuit precedent provide an independent basis to dismiss Defendants' Motion, which raises factual disputes and requires resolution of a claim construction dispute. But more importantly, the very fact that Defendants are seeking a finding that their IQOS[®] system does not infringe—based on *Defendants'* claim construction arguments and *Defendants'* interpretation of certain evidence—makes certain that Healthier Choices' Complaint more than meets the pleading standard set forth in Rule 8, and Defendants' Motion should be denied.

Defendants' Motion hinges entirely on their allegation that Healthier Choices' Complaint fails to allege a plausible claim for infringement because combustion cannot and does not occur in the IQOS[®] system. This is incorrect. First, Healthier Choices' Complaint plausibly states a claim for direct and indirect infringement, either literally or under the doctrine of equivalents. Second, Defendants' premature claim constructions are neither supported by Defendants' statements in the MRTPA Executive Summary, D.E. 1-10, nor the FDA Scientific Review of the MRTPA, D.E. 31-2, and are thus irrelevant.

A. Healthier Choices' Complaint States More Than a Plausible Claim for Relief for Patent Infringement

Healthier Choices sufficiently alleges combustion can and does occur. Healthier Choices' Complaint satisfies Rule 8 and the *Iqbal/Twombly* standard by particularly identifying Defendants' IQOS[®] system and by pleading a plausible

manner in which Defendants infringe each and every limitation of the '170 patent. Critical at this juncture, Healthier Choices' Complaint compares the claims of the '170 patent to admissions in Defendants' own public disclosures regarding the IQOS® system. The Federal Rules and controlling case law require nothing more.

1. Healthier Choices' Complaint Meets the Pleading Standard Because the Complaint Contains Plausible Allegations of Direct Patent Infringement

Healthier Choices' Complaint alleges that Defendants sought and received approval to import, distribute, market, offer for sale, sell, and/or instruct customers how to use the IQOS® system. Complaint at ¶¶ 33-34; *see also* D.E. 1-2 (FDA News Release) & D.E. 1-3 (FDA Marketing Order). Thereafter, Healthier Choices' Complaint alleges that Defendants infringe at least claim 1 of the '170 patent because the IQOS® system is 'an electronic pipe' that meets the limitations of at least claim 1 of the '170 patent, either literally or under the doctrine of equivalents[,]'' and the IQOS® system is imported, developed, manufactured, marketed, used, sold, and/or distributed in the United States, including this District. Complaint at ¶¶ 22, 24, 42, 44-47, 49; *see* '170 patent, 9:36 – 10:4. As pled, Healthier Choices plausibly alleges Defendants infringe and continue to infringe each of the elements of claim 1, either literally or under the doctrine of equivalents. Complaint at ¶¶ 44-55; *see Intendis, Inc. v. River's Edge Pharms., LLC*, C.A. No. 1:11-cv-01634-RLV, 2012 U.S. Dist. LEXIS 191772, at *9, n.1 (N.D. Ga. Aug. 23, 2012) (merely requiring the "complaint satisf[y] *Iqbal* and *Twombly*" for a motion to dismiss); *Auburn Univ. v.*

IBM, 864 F. Supp. 2d at 1225 (“a claim under the doctrine of equivalents can be brought through an allegation on direct infringement”).

At most, Defendants’ assertions amount to a mere allegation that “combustion” is “improbable.” *Swipe Innovations LLC v. NCR Corp.*, No. 1:13-CV-2219, 2013 WL 6080439, at *1 (N.D. Ga. Nov. 18, 2013) (“A complaint may survive a motion to dismiss for failure to state a claim . . . even if it is ‘improbable’ that a plaintiff would be able to provide those facts [and] even if the possibility of recovery is extremely ‘remote and unlikely.’” (quoting *Bell Atl.*, 550 U.S. at 556)). But “combustion” is a patent claim term that must be construed by the Court, and contrary to Defendants’ Motion, Healthier Choices identifies a plausible interpretation of combustion and thus, a plausible claim of infringement.²

As particularly pled, Defendants infringe directly and/or indirectly by loading combustible material into a material reservoir and initiating a combustion reaction in the combustible material reservoir. Complaint at ¶¶ 45-46, 50-52. Thereafter, at least partial combustion can and does occur in the chamber of the IQOS® system;

² Defendants reliance on *Griffin* is misplaced because the exhibits attached to the *Griffin* complaint refer to an earlier “administrative law judge decision attached to the complaint.” *Griffin Industries, Inc. v. Irvin*, 496 F.3d 1189, 1206 (11th Cir. 2007). In fact, the decision is used to demonstrate that two parties “were not . . . similarly situated . . .” *Id.* Here, the previously filed ’170 patent by Healthier Choices and the after-filed, post-patent issuance disclosure by Defendants cannot “plainly show” that Healthier Choices’ Complaint makes “general or conclusory allegations” let alone, that Healthier Choices’ allegations are implausible.

Defendants’ Motion fails to identify how or why combustion is improbable, let alone implausible, by citing to equivocal and conditional language. *Compare* Complaint at ¶ 52 (citing the Executive Summary at 40-41 (“the THS [(Tobacco Heating System)] aerosol contains substantially lower levels of HPHCs . . . reduced by over 97%”)) *and* Executive Summary at 20 (“THS generates a nicotine-containing aerosol by heating the tobacco in a manner that avoids combustion”) *with* FDA Scientific Review at 14, 75 (FDA classifies the device as “a novel tobacco product,” and thus, subject to “greater uncertainty”) *and* FDA Scientific Review at 9 (“[T]here were limitations in the design of these studies that created uncertainty in the interpretation of study findings, thereby limiting the conclusions that could be drawn from this evidence.”). In fact, a “secondary objective[]” of Defendants’ MRTPA was to “confirm the absence of combustion,” but the FDA only found that Defendants’ submission “suggest[s] that combustion does not occur.” *Compare* Executive Summary at 34 (requesting, as one “secondary objective[, to] confirm the absence of combustion”) *with* FDA Scientific Review at 21 (declining to confirm the absence of combustion, limiting FDA’s conclusion to a finding that Defendants’ submission provided sufficient evidence to support a statement that: “The IQOS system heats tobacco but does not burn it”).³

³ Defendants’ attempt to limit the scope of the terms “combustion” and “initiating a combustion reaction” in the ’170 patent is unavailing. *Moore* is misplaced because Healthier Choices is not attempting to read some scientific or inherent limitation out

As set forth in Healthier Choices’ Complaint, since at least as late as October 2019, Defendants have used and continue to manufacture, use, import, sell, offer to sell, market, and/or distribute the IQOS® system. Complaint at ¶ 37. As a result of Defendants’ infringement, Defendants have damaged and continue to damage Healthier Choices. Complaint at ¶ 58. Together, Healthier Choices’ pleadings demonstrate plausible assertions of infringement and provide adequate notice to Defendants.

of the disputed terms as used in the ’170 patent to claim Defendants infringe based upon the doctrine of equivalents. *Moore U.S.A., Inc. v. Standard Register Co.*, 229 F.3d 1091, 1106 (Fed. Cir. 2000) (“it would defy logic to conclude that a minority—the very antithesis of a majority—could be insubstantially different from a claim limitation requiring a majority, and no reasonable juror could find otherwise”). Here, the HeatStick is a combustible, solid, mixed tobacco-material that undergoes a chemical reaction. As a result of the chemical reaction—whether by heating, burning, igniting, combusting or some other extrinsic term of art—by-products are released from the IQOS® system. Further, it can hardly be said that Healthier Choices’ use of the term combustion is “the very antithesis” of Defendants’ FDA submissions implicating combustion—indeed, such an argument is contrary to Healthier Choices’ self-made, heating versus combustion scale: “nitrogen oxides (NO_x) and carbon monoxide (CO), **two important combustion markers[,]**” “[l]ower levels of HPHCs,” “heating the tobacco in a manner that **avoids** combustion,” and “the tobacco neither ignites nor burns [which] **prevents** combustion from occurring[.]” Memo at 9-10, 16, 17, 20.

2. **Healthier Choices’ Complaint Sufficiently Pleads Induced Patent Infringement**

Healthier Choices’ Complaint identifies “Defendants’ actions relating to the development, manufacture, importation, offer for sale, and sale of the [IQOS[®] system that] were done by and for the benefit of Defendants.” Complaint at ¶ 57. Specifically, Healthier Choices alleges that Defendants have committed⁴ and continue to commit acts of infringement by “making, using, selling, offering for sale, importing, advertising, and/or promoting products . . . that infringe one or more claims of the ’170 patent, and/or inducing others to commit such acts” Complaint at ¶¶ 9, 14-15, 17, 20-21, 29-32, 35-37, 43-57. As identified in the Complaint, Defendants “instruct customers how to use the [IQOS[®] system].” Complaint at ¶ 29; *see* D.E. 1-11 (IQOS Quick Start Guide); D.E. 1-12 (IQOS User Guide). By committing and continuing to commit acts of infringement, “Defendants know and specifically intend for the IQOS[®] system to be used in a manner that meets the limitations of at least claim[s 1 and] 5 of the ’170 patent, including by providing customers with a User Guide and/or a Quick Start Guide and/or instructing customers at retail locations.” Complaint at ¶¶ 42, 43, 49-56.

⁴ Unlike the Plaintiff in *Swipe*, Healthier Choices plausibly alleges that Defendants had the requisite knowledge of the ’170 patent and that its distributors’ and customers’ use of the Alleged Infringing product constituted infringement. *See Swipe Innovations*, 2013 WL 6080439, at *3 (dismissing pre-suit, indirect infringement claims where the complaint alleged defendant took steps “to cause infringement with both knowledge of the 296 patent and the specific intent to cause [the infringing acts]”). Here, Defendants had the requisite knowledge of the ’170

Regardless, Defendants appear to be confused between dismissal and damages. Whether Plaintiff is entitled to pre-suit relief is a damages issue rather than one related to the sufficiency of the allegations in the Complaint. *Compare* 35 U.S.C. § 287(a) (“In the event of failure so to mark, no damages shall be recovered by the patentee in any action for infringement, except on proof that the infringer was notified of the infringement and continued to infringe thereafter, in which event damages may be recovered only for infringement occurring after such notice.”) (emphasis added) with *Rembrandt Soc. Media, LP v. Facebook, Inc.*, 1:13-CV-158, 950 F. Supp. 2d 876, 882 (E.D. Va. June 12, 2013) (“[T]here is an important consequence of relying on the filing and service of the infringement suit to satisfy the knowledge requirement to establish indirect infringement: Plaintiff may only recover damages for indirect infringement for the period of time that commences once the putative infringer learns of the patent.”). If discovery reveals that Defendants had notice that their IQOS[®] system infringes the ’170 patent prior to

patent either because Defendants were aware of the ’170 patent during prosecution of their “novel patented tobacco product” or Defendants were willfully blind to scientific data identifying combustion within their IQOS[®] system and thus, willfully blind to knowledge of the ’170 patent. *See* Complaint at ¶ 46 (“Defendants’ own testing concludes that . . . the presence of 3% of the two important combustion markers[,] nitrogen oxides and carbon monoxide[,] indicates that at least some combustion occurs when the [IQOS[®] system] is operated as designed and intended by Defendants.”); the Executive Summary at 20 (a “patented novel tobacco product”). Regardless, the Court in *Swipe* recognized that defendants’ “requisite knowledge post-filing [was] sufficient.” *Swipe Innovations*, 2013 WL 6080439, at *3.

November 30, 2020, then Healthier Choices will be entitled to damages based on indirect infringement prior to that date. Complaint at ¶¶ 41, 43-48, 50-56; *Swipe Innovations*, 2013 WL 6080439, at *3; *Rembrandt Soc. Media*, 950 F. Supp. 2d at 882, n.5. If not, then Healthier Choices' damages for indirect infringement may be limited to post-November 30, 2020, conduct. Accordingly, Defendants' motion to dismiss Healthier Choices' indirect infringement claim should be denied.

B. The Parties' Claim Construction Dispute Cannot Be Resolved on a Motion to Dismiss

Defendants' Motion relies on the mistaken assumption that the FDA Scientific Review demonstrates combustion cannot and does not occur. D.E. 31-1, Defendants' Memorandum in Support of Their Motion to Dismiss Under Fed. R. Civ. P. 12(b)(6) ("Memo") at 20 ("establish[ing] that this assumption is implausible."); Memo at 21 ("no combustion actually occurs in [the IQOS® system]"). According to Defendants, the definitions of claim terms "combustion" and "initiating a combustion reaction" are "conclusively establish[ed]" by the FDA such that they confirm the terms' construction in the '170 patent. *See* Memo at 2, 8 ("The '170 patent supports no other colorable interpretation of 'combustion reaction'"); *see also* Memo at 16 (stating Plaintiff's construction is a "speculative, implausible claim"); Memo at 20 (asserting Plaintiff's claim is an "unsupported and implausible assumption that combustion is the only possible explanation").

Recognizing that Defendants' Motion is coming before this Court's claim

construction ruling—and clearly, prior to exchanging proposed claim terms—Defendants urge the Court to conclusively adopt Defendants’ constructions as the only plausible theory. *See, e.g.*, Memo at 2 (“Plaintiff’s theory is implausible on the merits” and “no amended pleading can cure its shortcomings”); Memo at 18-19 (lacking a “plausible, internally coherent, complaint”); Memo at 21 (asserting “no deference is due Plaintiff’s implausible allegation”); Memo at 24 (“Plaintiff has presented a claim so implausible that it has pled itself out of court.”). However, Defendants improperly rely on extrinsic evidence under the guise of judicial notice in an attempt to prematurely construe the term “combustion” and thus, Defendants’ Motion must be dismissed.

First, Defendants’ reliance on the FDA Scientific Review pursuant to judicial notice is improper. Defendants rely on the FDA Scientific Review to demonstrate the truth of a fact-in-dispute—that combustion cannot and does not occur—in an attempt to prematurely request that the Court decide all issues as a matter of law. Defendants’ reliance is improper because judicial notice enables the court to take notice of documents that are not in dispute. *See Funk v. Stryker Corp.*, 631 F.3d 777, 783 (5th Cir. 2011) (“there was no actual asserted **factual dispute**”). Indeed, no court has construed the claims of the ’170 patent, and Healthier Choices clearly disputes, at least, the construction of the terms “combustion” and “initiating a combustion reaction.”

Defendants’ contention that their IQOS[®] system does not initiate a combustion reaction as defined or approved by the FDA, post-patent issuance, is inconsequential at this stage of the proceeding. While the Court need not reach this issue to resolve Defendants’ Motion, (*Nalco*, 883 F.3d at 1349), it would be error for the Court to adopt the same constructions for the combustion terms in the ’170 patent as in the Executive Summary or FDA Scientific Review. When properly construed, the terms “combustion” and “initiating a combustion reaction” will not be measured by or in accordance with Defendants’ post-patent issuance, self-serving submissions. The ’170 patent has different claim language, with different context, submitted years if not decades apart. This difference is outcome-determinative to Defendants’ non-infringement argument, which depends on the disputed terms “combustion” and “initiating a combustion reaction” having the same meaning in the ’170 patent and Defendants’ post-patent issuance, self-serving disclosures. Therefore, whether combustion occurs in the IQOS[®] system is a question of fact, and the proper construction of the term “combustion” is a question of law. In pursuit of Defendants’ premature construction, Defendants impermissibly rely on a disputed fact in extrinsic evidence—the FDA Scientific Review—requiring dismissal of Defendants’ claim for at least this reason. *Novartis Pharm. Corp. v. Actavis, Inc.*, No. CIV.A. 12-366-RGA, 2012 WL 6212619, at *5-6, *8 (D. Del. Dec. 5, 2012) (finding “disposal of its infringement claims . . . would be premature at this stage”

when ruling in favor of Defendants “would require the construal of some of the patent’s claim terms and (likely) the consideration of extrinsic evidence—processes that should not come into play at the pleadings stage of a case”).

Second, the FDA Scientific Review neither provides a definition for the term “combustion” nor concludes that the IQOS® system cannot and does not initiate a combustion reaction. *See infra* Section IV.A.1. Defendants’ Motion rests solely on its contention that, because its IQOS® system is labeled by the FDA as a heat-not-burn device, the IQOS® system cannot initiate a combustion reaction. Memo at 2, 15-20. Defendants miss the point. Approval of a reduced-risk, heat-not-burn device by the FDA under §§ 911(g)(1) and/or 911(g)(2) does not require a conclusion that combustion cannot and does not occur; tellingly, Defendants do not dispute that Defendants’ accused “heat-not-burn” IQOS® system generates chemicals such as nitrogen oxides and carbon monoxide that are indicative of combustion. Thus, the Court should deny Defendants’ Motion filed prior to claim construction and expert discovery. *See, e.g., Nalco*, 883 F.3d at 1349-50 (finding unresolved claim construction issues not suitable for resolution on a Rule 12(b)(6) motion to dismiss); *Spanakos*, 2018 WL 2392011, at *5 (denying motion to dismiss because “[i]t would be premature to engage in [a claim construction and infringement] analysis at the

motion to dismiss stage.”).⁵

Defendants’ hasty Motion seeks to have the Court prematurely rule not only on Defendants’ preferred, limited construction of select terms from claims 1 and 5 of the ’170 patent, but also on whether various components of the IQOS[®] system infringe one or both of these claims, literally or under the doctrine of equivalents. Memo at 1-2, 18-19, 22-23. Because Defendants improperly rely on a disputed fact in extrinsic evidence, let alone a fact that is not supported by the extrinsic evidence upon which Defendants rely, the Court should deny Defendants’ request to prematurely resolve Healthier Choices’ plausible construction of claim terms, and therefore, deny Defendants’ Motion.

V. IN THE ALTERNATIVE, HEALTHIER CHOICES SHOULD BE GRANTED LEAVE TO AMEND ITS COMPLAINT

Based on the foregoing, Healthier Choices submits that its Complaint, as written, provides Defendants more than adequate notice of the claimed infringement. Nevertheless, if the Court believes that the Complaint does not sufficiently plead its

⁵ In *Nalco*, the Federal Circuit reversed a district court’s dismissal of Nalco’s infringement claims because that dismissal required resolution of a claim construction dispute, which “was inappropriate at the Rule 12(b)(6) stage of the proceedings.” *Id.* at 1349. Similarly, district courts have denied motions to dismiss because it “would be premature to engage in [claim construction] at the motion to dismiss stage.” *Spanakos*, 2018 WL 2392011, at *5; see *Automated Transaction Corp. v. Bill Me Later, Inc.*, No. 09-cv-61903, 2010 WL 1882264, at *4 (S.D. Fla. May 11, 2010) (“absent agreement of the parties that claim construction should be done now, prior to discovery, the Court will defer its claim construction to a later date in this case.”).

patent infringement claim with necessary facts, then Healthier Choices requests that the Court grant Plaintiff leave to amend its Complaint.

“The decision whether to grant leave to amend is committed to the sound discretion of the trial court. However, ‘discretion’ may be a misleading term, for rule 15(a) severely restricts the judge’s freedom, directing that leave to amend shall be freely given when justice so requires.” *Espey v. Wainwright*, 734 F.2d 748, 750 (11th Cir. 1984) (per curiam) (internal citations and quotation marks omitted). “[U]nless there is a substantial reason . . . the discretion of the district court is not broad enough to permit denial.” *Id.* at 750.

In this instance, there is no substantial reason to deny Plaintiff’s request in the alternative for leave to amend. *See Miller v. Gould*, No. 1:06-CV-2039-CC, 2008 U.S. Dist. LEXIS 23460, at *4-5 (N.D. Ga. Mar. 20, 2008) (“In the absence of any apparent or declared reason—such as undue delay, bad faith or dilatory motive on the part of the movant, repeated failure to cure deficiencies by amendments previously allowed, undue prejudice to the opposing party by virtue of allowance of the amendment, futility of amendment, etc.—the leave sought should, as the rules require, be ‘freely given.’”) (quoting *Foman v. Davis*, 371 U.S. 178, 182 (1962)). As described above, amendment or supplementation of the Complaint would not be futile.

Amending the Complaint would also cause no “undue prejudice” to Defendants. *See ITC Deltacom Commc’ns. v. US LEC Corp.*, No. 3:02-CV-116 JTC, 2004 WL 3709999, at *10 (N.D. Ga. Mar. 15, 2004) (concluding amendment of a complaint at the end of a discovery period would not prejudice defendant where substantive claims were unchanged). Here, *discovery has not opened*, depositions have not been scheduled, and no pre-trial conference or trial date has been set. Granting leave to amend would be appropriate under the circumstances because this case is still at the pleadings stage.

VI. CONCLUSION

For the foregoing reasons, Healthier Choices respectfully requests that the Court deny Defendants’ Motion. Alternatively, if the Court believes that any of Plaintiff’s claims are legally insufficient, the Court should provide Plaintiff with leave to amend its pleading and supplement its existing allegations at this time.

Dated: March 22, 2021

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

Pursuant to L.R. 7.1D the undersigned hereby certifies that the foregoing document has been prepared in Times New Roman 14 point, one of the four fonts and points approved by the Court in L.R. 5.1C.

/s/ Alycen Moss
Alycen Moss

CERTIFICATE OF SERVICE

The undersigned hereby certifies that on March 22, 2021, the foregoing document was filed with the Clerk of the Court using CM/ECF, which will send electronic notification of such filing to all counsel of record.

/s/ Alycen Moss
Alycen Moss